

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION <hr/> THIS DOCUMENT RELATES TO THE FOLLOWING PLAINTIFFS: Christin Wiltgen Case No. 2:12-cv-01216 Laura Waynick Case No. 2:12-cv-01151 Denise Burkhart Case No. 2:12-cv-01023 Debra A. and Donald Schnering Case No. 2:12-cv-01071 Karen Bollinger Case No. 2:12-cv-01215	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**REPLY IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE
THE TESTIMONY OF KIMBERLY KENTON, M.D., M.S.**

Plaintiffs now come in reply to Defendant Ethicon, Inc's (Ethicon") Opposition to Plaintiffs' Motion to Exclude the Testimony of Dr. Kimberly Kenton, M.D., M.S. ("Dr. Kenton") and memorandum in support thereof. Despite their claims to the contrary, Ethicon has not proffered evidence to support the proposition that Dr. Kenton is qualified to discuss the engineering and biomechanical properties of polypropylene mesh nor has it offered this Court support for its bald assertions that there are no differences in complication rates between laser-

cut and mechanically-cut TVT devices.¹ Therefore, this Court should grant Plaintiffs' *Daubert* Motion and preclude the testimony of Dr. Kenton as set forth therein.

A. Dr. Kenton is not qualified to proffer opinions regarding the chemical, structural, or biomechanical makeup of the TVT device or of any of its component parts and all of her opinions related to such must be excluded.

Dr. Kenton's expert report(s) include numerous opinions that Dr. Kenton, as a practicing urogynecologist with no training in chemical or structural engineering and/or in biomechanics, is simply unqualified to render. Ethicon's brief fails to provide the Court with any evidence or specific information that would allow the Court to conclude that Dr. Kenton is an expert on these *particular* characteristics of polypropylene mesh. Instead, of addressing the specific design issues raised in Plaintiffs' initial brief, Defendant quickly attempts to redefine the role of Dr. Kenton-- to be limited to discussing the clinical safety and efficacy of the TVT device. However, Dr. Kenton's reports and deposition testimony make clear that such limitation was never intended by Dr. Kenton.

In sole support of her purported qualifications to discuss the design elements of TVT raised by Plaintiffs' brief, Ethicon relies upon the general statement that "Plaintiffs ignore Dr. Kenton's testimony that although she was not formally contracted as a consultant on design of transvaginally placed mesh products, she has informally participated in the design process." (Def. Br. at 6.) However, neither Defendant nor Dr. Kenton explain what "informal" participation means or how it qualifies Dr. Kenton to testify about the structural engineering and biomechanical properties of polypropylene mesh. Absent such a link, this Court is left with no support for the Ethicon's assertion that Dr. Kenton is qualified to discuss design elements of the TVT device.

B. Dr. Kenton failed to review her own clinical data on the differences in outcome between mechanically-cut and laser-cut TVT and, therefore, any opinions based merely upon her own perception of her experience is invalid.

¹ Plaintiffs' reply is limited to the two particular issues raised by Defendant's opposition brief. Plaintiffs stand by their original papers for all other areas not specifically covered by this additional pleading.

In its opposition, Ethicon asserts that Dr. Kenton is able to testify to the safety and efficacy of mechanically-cut TVT devices in comparison to laser-cut TVT devices because of her clinical experience and review of the literature.(Def. Br. at 7.) (“Dr. Kenton, based upon her extensive and regular review of clinical literature and outcomes in her own clinical practice, states that there is no reliable clinical data showing that there is any difference between the two.”)

This Court has previously precluded this sort of “I have not seen it, therefore it must not happen” testimony. In rejecting such faulty logic, this Court noted:

Author and astronomer, Carl Sagan, popularized the aphorism, “Absence of evidence is not evidence of absence.” Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 213 (1996). Sagan’s aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan’s musings are relevant here because for the first time during these MDLs, the plaintiffs have challenged the defendant’s attempt to offer experts seeking to opine on the adequacy of product warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs’ experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC’s experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs’ experts address a discrete risk which they have personally observed, while BSC’s experts’ opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice.

Tyree v. Boston Scientific Corp., Case 2:12-cv-08633, Dkt. No. 444, p. 118 (*Daubert* Order).

Moreover, under the Court's holding, a doctor's personal experience claiming to have not observed a difference between mechanically and laser-cut meshes cannot serve as a reliable scientific basis for rendering an expert opinion in federal court that, *ergo*, there is no difference. Very simply, "Absence of evidence [of a meaningful clinical difference] is not evidence of absence [of a clinical difference]." Thus, this unscientific testimony should be excluded.

However, should Dr. Kenton seek to offer the opinion that there is no difference between the two types of mesh, the record reveals that Dr. Kenton's experience and literature review are insufficient to form opinions on the differences between laser and mechanically cut mesh. First, as Defendant concedes, Dr. Kenton only relied upon one study on this issue, "because it was 'the only one that's out there.'" (Def. Br.8.) (internal citations omitted.) Thus, as Plaintiffs explained in her prior brief there is no basis in this one article to support Dr. Kenton's opinions on these two types of mesh.

More importantly, Defendant states, "Dr. Kenton bases her opinions on mechanical- and laser- cut TVT...on her own extensive experience." *Id.* While her clinical experience may, if appropriately tracked, be the source of objective opinions, it cannot support her current opinions in this case because Dr. Kenton never actually looked at her own internal clinical data to assess whether there was a difference between the two versions of TVT devices. Despite being "easy to assess outcomes of mechanical- cut and laser-cut in her practice," Dr. Kenton never reviewed the data. (Def. Br. At 7.) (See also Exhibit B to Def. Br.) Because she didn't actually review any data, her opinions as to what her clinical data *might* have shown are nothing more than guesswork requiring preclusion under *Daubert*.

C. Conclusion

For the foregoing reasons, Plaintiffs request that this Court grant Plaintiffs' motion to exclude the testimony of Dr. Kimberly Kenton under *Daubert*.

This 16th day of May, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on May 16th, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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